MAY 0 7 2016



## 510(k) SUMMARY

**Submitter Information**

| | |
|---|---|
| Name: | Sofradim Production (subsidiary of Covidien LLC) |
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| Establishment Registration: | 9615742 |
| Name of contact person: | Clare Santulli<br>Manager, Regulatory Affairs Covidien<br>60 Middletown Avenue<br>North Haven, CT 06473 |
| Phone: | 203-492-7635 |
| Date prepared: | April 11, 2014 |

**Name of device:**

| | |
|---|---|
| Trade or proprietary name: | PROGRIP™ Self-Gripping Polypropylene Mesh<br>Parietene™ Flat Sheet Mesh |
| Common or usual name: | Surgical Mesh |
| Classification name: | Mesh, Surgical, Polymeric |
| **Classification panel:** | General and Plastic Surgery (79) |
| **Regulation:** | 21 CFR 878.3300 |
| **Product Code:** | FTL |

**Legally marketed devices to which equivalence is claimed:**

PARIETENE™ PROGRIP™ Mesh (K101197)

PARIETENE™ Polypropylene Mesh (K991400)

**Reason for 510(k) Submission:**

The purpose of this 510(k) is to notify the agency of the addition of another formulation of raw material, polypropylene, from the yarn supplier who manufactures the monofilament yarns used in the proposed devices. Eventually the current polypropylene will no longer be available by the supplier.

**Device description:**

PROGRIP™ Self-Gripping Polypropylene Mesh

The mesh and the overlapping flaps of the pre-cut versions are made of knitted monofilament polypropylene with polylactic acid monofilament resorbable hooks on one of the sides. These hooks facilitate placing, positioning and temporary fixation of the overlapping flap and the mesh to the surrounding tissue.
A colored yarn marker is placed on the medial edge of the pre-cut mesh to help with orientation.

Parietene™ Flat Sheet Mesh

Parietene™ Flat Sheet Mesh is a Monofilament polypropylene mesh.

**Intended use of the device:**

PROGRIP™ Self-Gripping Polypropylene Mesh

PROGRIP™ Self-Gripping Polypropylene Mesh is intended for the reinforcement of tissue during surgical repair.

No changes to the intended use have been made in this submission.

Parietene™ Flat Sheet Mesh

Parietene™ Flat Sheet Mesh is intended for the reinforcement of tissue during surgical repair.

No changes to the intended use have been made in this submission

**Indications for use:**

PROGRIP™ Self-Gripping Polypropylene Mesh

PROGRIP™ Self-Gripping Polypropylene Mesh is indicated for inguinal and incisional hernia repair.

No changes to the indication for use have been made in this submission

Parietene™ Flat Sheet Mesh

Parietene™ Flat Sheet Mesh is indicated for inguinal hernias, parietal reinforcement of tissues and abdominal wall hernia repair.

No changes to the indication for use have been made in this submission

**Summary comparing the technological characteristics of the subject and predicate devices:**

The proposed PROGRIP™ Self-Gripping Polypropylene Mesh and Parietene™ Flat Sheet Mesh manufactured with another formulation of raw material, polypropylene, from the same yarn supplier as the current polypropylene are equivalent to predicate Parietene™ PROGRIP Mesh (K101197) and Parietene™ Polypropylene Mesh (K991400) in terms of the following technological characteristics:

- Indication
- Raw materials
- Performance characteristics
- Biocompatibility
- Stability

**Performance data:**

This change consists of the addition of another formulation of raw material, polypropylene, for the subject devices.

Bench testing has been conducted in accordance with *FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh* issued March 2, 1999 to evaluate the performance characteristics of the proposed devices.

Stability Studies have been conducted and the proposed devices shelf life has been demonstrated.

Biocompatibility studies have been conducted on the proposed polypropylene devices in accordance with ISO 10993-1 for a permanent implant, a recognized standard by FDA (#2-156).

**Conclusion:**

The results of the bench and preclinical tests demonstrate that proposed devices are substantially equivalent to the predicates Parietene™ PROGRIP Mesh (K101197) and Parietene™ Polypropylene Mesh (K991400)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2014

Sofradim Production
% Ms. Clare Santulli
Regulatory Affairs Manager, Covidien
60 Middleton Avenue
North Haven, Connecticut 06473

Re: K140941
Trade/Device Name: PROGRIP™ Self-Gripping Polypropylene Mesh, Parietene™ Flat Sheet Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: April 11, 2014
Received: April 14, 2014

Dear Ms. Santulli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140941

Device Name
PROGRIP™ Self-Gripping Polypropylene Mesh

Parietene™ Flat Sheet Mesh

Indications for Use *(Describe)*
PROGRIP™ Self-Gripping Polypropylene Mesh is indicated for inguinal and incisional hernia repair.

Parietene™ Flat Sheet Mesh is indicated for inguinal hernias, parietal ereinforcement of tissue and abdominal wall hernai repair.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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